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EXAMINER	
WESTERBERG, NISSA M	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,882	PRASCH ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 20* is/are pending in the application.

4a) Of the above claim(s) *10, 13, 15 - 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 9, 11, 12 14* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I and species of polyoxypropylene polyoxyethylene condensates or block polymerisates (for example a poloxamer), macrolide antibiotics (for example azithryomycin or clarithromycin) and no coating being present in the reply filed on January 15, 2008 is acknowledged.

2. During a telephone conversation with Randolph Huis on February 27, 2008 the first two species elections were clarified to be a solutizer of polyoxypropylene polyoxyethylene condensates and the hard to dissolve effective agent as macrolide antibiotics. Affirmation of this election must be made by applicant in replying to this Office action.

Specification

3. The disclosure is objected to because of the following informalities: on page 19, paragraph [0068], it is stated that "references are given in Fig. 1." This seems to indicate that references to patent literature or scientific publications are presented in figure 1. While reference characters are present in the figure, they are fully discussed later in the specification.

Appropriate correction is required.

4. The disclosure is objected to because of the following informalities: in what appears to be literal translation, the word "explosives" is used in paragraph [0047] to describe materials such as starches, carboxy methyl starches, cross-linked polyvinyl pyrrolidon, aligne acid or a salt thereof. These examples are not compounds normally described in English as explosives.

Appropriate correction is required.

Claim Objections

5. Claim 5 is objected to because of the following informalities: the word "analgetics" appears in line 5 of this claim. This appears to be a typographical error and that applicant intended "analgesics which are hard to dissolve in water".

Appropriate correction is required.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 1, 5 and 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 21 of copending Application No. 11/876,214 in view of Schutte et al. (US Patent 6,159,252). Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass overlapping subject matter. The claims of the instant

application recite a method of producing micropellets that comprise a hard to dissolve effective agent such as a macrolide antibiotic and functional adjuvants made by spray granulation in a fluidized bed process. Further steps such as coating the micropellets are not precluded. Claim 21 of '214 recite a process for preparing coated pellets comprising a macrolide antibiotic and additive(s) (the adjuvants of the instant application) that is granulated and then coated but does not recite the method by which the granulate is made.

Schutte et al. teaches that liquid products (such as suspensions, solutions or even melts) can be converted into a granular solid by fluidized bed spray granulation (col 1, ln 11 – 14).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the fluidized bed spray granulation process taught by Schutte et al. to prepare granulated particles comprising an antibiotic and a functional adjuvant. That resulting process of producing a particle comprising the hard to dissolve effective agent (the at least one macrolide antibiotic) and adjuvants lies within the scope of the claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112 1st Paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1 – 9, 11, 12 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to effective agents which are "hard to dissolve". No indication is given in the specification as to what properties an effective agent must have in order to be hard to dissolve. For example, the solvent (either a specific solvent, hydrophobic solvents in general or hydrophilic solvents in general) or the time, temperature, and/or pH required in order to achieve a particular dissolution level of the effective agent that would cause an effective agent to be classified as "hard to dissolve" is not described.

Claim Rejections - 35 USC § 112 2nd Paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1 – 9, 11, 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. "Hard to dissolve effective agent" is never defined. If a compound is highly soluble in an aqueous solvent, it will be hard to dissolve in an organic solvent and if it is highly soluble in an organic solvent, it

will hard to dissolve in an aqueous solvent. A compound could be slightly soluble in both organic and aqueous solvents and thus can be hard to dissolve in both solvent systems. It appears that Applicant is attempting to limit the claims to only some effective agents, but the term "hard to dissolve" does not impose any limitations on the effective agents. Therefore the metes and bounds of the claims cannot be determined because it is unclear if all effective agents or only some are included in the scope of the claims.

12. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The first Markush group for the effective agents begins with "macrolide antibiotics, comprising azithromycin, antiviral therapeutics..." A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86

USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation of macrolide antibiotics, and the claim also recites the specific macrolide antibiotic azithromycin which is the narrower statement of the range/limitation. This interpretation of the broad range "macrolide antibiotic" being present in claim 5 and not necessarily azithromycin is reinforced by dependent claim 6 wherein the specific effective agent clarithromycin, also a macrolide antibiotic, is claimed.

13. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the claim, the fluidized bed arrangement should be empty at the beginning of the process. Unless the apparatus is located inside a vacuum chamber, the appartus will be at least filled with air at the beginning of the process. In the second paragraph, the spray granulation of the dispersion is started with the absence of any other inert material. While this could be interpreted to means the absence of inert cores to aid in the granulation process, it could also mean that the spray granulation is carried out in a vacuum as the inert gas inside the apparatus has been removed.

14. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the first separate step (ln 3 – 8) of this claim a homogenous suspension (paragraph 2) containing the effective agent is prepared. The difference between "several respective effective agents" and "a respective mixture of effective agents" in this step is unclear. In another separate step (ln 9 – 12; paragraph 3) a homogenous solution of the adjuvants and other components is prepared.

In paragraph 2, the mixer is "for homogenizing and/or deaerating the dispersion" so either one or both processes may occur. However, immediately following that statement, the water is under both deaeration and homogenization. Also, in the final two lines of the claim, "the mixture and the deaeration" are simultaneously carried out. It is unclear whether both deaeration and mixing/homogenizing are required at for all steps recited, or only one must be occurring in the one step but is required in the other or if both are optional in all steps.

What is done with the resulting mixtures from paragraph 2 and 3 is described in lines 13 – 19 but it is not clear how the homogenous liquid dispersion develops. It seems that the solution from paragraph 3 is introduced into the device and is then mixed with the solution from paragraph 2. The claim goes on to state that the mixing and deaeration occur simultaneously. In the devices used to make granulations, the interior of the device can contain air so how the deaeration could be carried out inside the device is confusing.

Additionally, advantageous means of developing the liquid dispersion are present in lines 15 and 16. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite,

since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). It is unclear whether powder wetting or dispersing devices are required (narrower range) or if such devices are not required so long as homogenous liquid dispersion develops.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1, 2, 5, 8, 9, 11, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Upadhyay (US Patent 6,264,983).

Upadhyay discloses a method for preparing an acetaminophen granulation composition (col 2, ln 14 – 16), which is inherent a pharmaceutical formulation. The analgesic acetaminophen is a hard to dissolve effective agent as it is very slightly soluble in cold water (Merck Index entry for acetaminophen). The acetaminophen and a dispersion of the adjuvant particles in air are prepared prior to the introduction of a binder solution into the top spray fluid bed granulator (col 2, ln 18 – 31). A dispersion can consist of a solid in a gas as evidenced by the definition of dispersion from 14th Edition of Hawley's Chemical Condensed Dictionary. The composition comprises 80 – 95% by weight of the composition, so the amount of functional adjuvants ranges from 5 – 20% by weight (col 2, ln 58). Thus the ratio of adjuvant to effective agents ranges from 1:4 and 1:19 and that range is fully encompassed by the range presented in claim 2. A binder identified in the instant application is polyvinyl pyrrolidone (PVP, paragraph [0027]). PVP is present in the acetaminophen composition in an amount ranging from 0.5 – 5% (col 2, ln 63). The binder solution contains water which is dried after being sprayed into the fluid bed granultor (col 2, ln 27 – 32).

The size of the particles produced in example 5 is shown in col 11, ln 55 – 62. 13.6% of the particles were retained by a 60 U.S. Mesh screen which retains particles larger than 250 μm (see Particle Size/Screen Mesh comparison table). 96.8% of the particles were retained by a 325 U.S. Mesh screen which retains particles larger than 44 μm and the granulated particles are spherical, meeting the limitations in claim 12.

17. Claims 1 – 3, 8, 11, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Appel et al. (EP 1027887, cited on PTO-1449).

Appel et al. discloses controlled release dosage forms of low solubility drugs (paragraph [0012]). "Low solubility drug" is defined in paragraph [0020] as being either substantially water-insoluble or sparingly water soluble. The drug is dispersed in a solid dispersion polymer (paragraph [0017]) and can include compounds from a large number of drug classes (paragraph [0022]). The solid dispersion polymer generally contains about 5% to about 90 wt% of the drug (paragraph [0037]), leaving about 10% to about 95% of the solid dispersion being non-active ingredients.

The dispersion polymer is a polymer that is soluble in solvents that can be used in conjunction with techniques such as spray-drying (paragraph [0026]). This solid dispersion corresponds to the micronized particles of the instant claims. In spray-drying, liquid mixtures are rapidly broken up into small droplets in a vessel such as a fluidized bed apparatus (paragraph [0043]) to yield particles which are on the order of 1 to 100 μm in diameter (p 7, ln 27 – 28). The sprayed solution can contain only the drug and polymer (paragraph [0047]).

In example 1 (paragraph [0076]), a solution of a low solubility glycogen phosphorylase inhibitor and dispersion polymer was prepared and spray-dried. The dispersion polymer is the functional adjuvant and in this example, the weight ratio of the functional adjuvant to the effective agent is 2:1. The solvent used in this solution is acetone, which does contain water, so a homogenous suspension of the effective agents is produced in water as required in claim 8. As described above, the droplets

that results from the spray drying process have diameters between 1 and 100 μm so the limitation of claim 3 as to the grain size of the micronized form being 30 μm or less is met and as droplets are in a spherical form. Since the ingredients of the composition are a pharmaceutically effective ingredient and a dispersion polymer taught in the prior art is non-toxic, the resulting product is inherently a pharmaceutical formulation.

In claim 7, it is required that the fluidized bed apparatus be empty at the beginning of the process. When starting to produce something, the machinery to be used should be clean and empty of any other materials. This is particularly true when making a product on equipment that has been used previously to prepare a composition with a different effective agent. It is also required that no inert material is present when the starting seeds for pelletizing is started. No starter seeds are present in the procedure described to make the drug dispersion so this limitation is met.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 1, 5, 6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Appel et al.

As discussed above, Appel et al. discloses a process of spray-drying to form a solid dispersion comprising a low solubility effective agent and an adjuvant. No examples are provided in which a macrolide antibiotic is used in such a composition or a binder is included in the solid dispersion.

Macrolide antibiotics such as azithromycin, clarithromycin, erthyromicin and spiramycin are exemplified as low solubility effective agents (p 5, ln 29 – 30). The presence of other excipients such as binders is disclosed and can be included in the spray solution co-dissolved in the solvent with the drug or suspended in the solution containing the drug (paragraph [0048]).

Appel et al. teaches that the macrolide antibiotics, including the specific drugs azithromycin and clarithromycin, are among the many low solubility agents that may be made into a solid dispersion using the techniques described. Preparation of such a solid dispersion (micronized particles) by the method described would have been obvious to one of ordinary skill in the art at the time of the instant invention.

22. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Appel et al. as applied to claims 1 – 3, 5, 6, 11, 12 and 14 above, and further in view of Clancy et al (WO 97/02017).

As discussed above, Appel et al. discloses a process of spraying a liquid to form a solid dispersion comprising a low solubility effective agent and an adjuvant (solid dispersion polymer). That polymer should be soluble in solvents that are useful for spray-drying are processable in a "non-aqueous solvent" that can comprise up to about 30 wt% water (p 5, ln 42 – 48 of Appel et al.) since the drug is not highly soluble in the aqueous phase and the polymer and the drug must be dissolved in a common solvent to form the dispersion (p 5, ln 49 – 52 of Appel et al.).The use of a polymer consisting of a polyoxypropylene polyoxyethylene condensate (polymer) is not disclosed.

Clancy et al. discloses a solid dispersion of a poorly soluble active ingredient in a hydrophilic poloxamer polymer (p 2, ln 17 – 19) that significantly increases the solubility/wettability of the active ingredient in the dispersion (p 2, ln 24 – 27). Specific examples of such drugs include cisapride, nicardipine and nifedipine (abstract). The weight ratio between the active ingredient and poloxamer ranges from 0.1:1.0 to 10.0:1.0 (p 3, ln 28 – 29). The poloxamer polymers described by Clancy et al. are copolymers of polyoxyethylene and polyoxpropylene (p 4, ln 5 – 9) that are sold under trademarks such as LUTROL®, MONOLAN® and PLURONIC® (p 4, ln 20 – 22).

Appel et al. teaches that a solid dispersion of drugs with low solubility can be obtained by spraying a solution of the low solubility drug with a solid dispersion polymer. Clancy et al. teaches that low solubility active ingredients can made into a solid dispersion in combination with polyoxypropylene polyoxyethylene polymers. Both Appel et al. and Clancy et al. discloses the same type of poorly soluble drugs from many different therapeutic classes (such as the gastrointestinal agent cisapride (p 5, ln 21 – 22 of Appel et al.), the antihypertensive nifedipine (p 4, ln 58 of Appel et al.) and the vasodilator nicardipine (p 2, ln 30 of Appel et al.)).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a solution of polyoxypropylene polyoxyethylene as the dispersion polymer with the poorly water soluble active agent and prepare a solid dispersion using the method taught by Appel et al.

23. Claims 1, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Appel et al. as applied to claims 1 – 3, 5, 6, 11, 12 and 14 above, and further in view of Glad (WO 01/03809).

As discussed above, Appel et al. discloses a process of spraying a liquid solution to form a solid dispersion comprising a low solubility effective agent and an adjuvant (solid dispersion polymer). Appel et al. does teach that the solvent is removed by evaporation in the process of spray-drying (p 7, ln 28 – 30) but not in conjunction with a classification device that removes particles of a certain size from the apparatus.

Glad discloses a filter (classification device) for a fluidized bed system that separates particles larger than a particular size from the other particles in the fluid flow of the system (p 1, ln 4 – 6). The system to which this filter is attached is capable of drying, granulating or coating (p 4, ln 12 – 15).

Even if the apparatus is used to coat particles that have already been generated, the injection of the liquid dispersion need not occur after the introduction of the particles to be coated and could be started first so the fluidized bed apparatus is empty of the other components of the composition at the beginning of the process. The addition of a classification such as the filter device taught by Glad is known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to used a fluid bed apparatus to generate a solid dispersion using the method taught by Appel et al. and use a filter device such as that taught by Glad to remove particles of a certain size or larger from the apparatus.

Conclusion

Claims 1 – 9, 11, 12 and 14 are rejected. Claim 5 is objected to. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW